भारतीय मानक **IS 11704 : 2023**

Indian Standard

खाद्य सामग्री, फार्मास्यूटिकल्स और पेयजल के संपर्क में उनके सुरक्षित उपयोग के लिए इथाईलीन एक्रायलिक एसिड (ईएए) कॉपोलिमर — विशिष्टि

(पहला पुनरीक्षण)

Ethylene Acrylic Acid (EAA) Copolymers for their Safe Use in Contact with Food-Stuffs, Pharmaceuticals and Drinking Water — Specification

(First Revision)

ICS 83.080.20

भारतीय मानक ब्यूरो
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Plastics Sectional Committee, PCD 12

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Plastics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was originally published in 1986. This revision has been undertaken to update the cross referred standards.

Ethylene acrylic acid (EAA) copolymers are produced with varying acrylic acid content, 3 percent to 25 percent, and melt indices from 1 to 3 000 depending on the fabrication method and the end use application requirements. By precise control of copolymerization process and recipes, copolymers with precise molecular design and accurate co-monomer content are produced which are competitive and have improved adhesives properties.

EAA copolymer product range consists of a low melt index group of copolymers for extrusion coating, blown and cast film production and a high melt index family of polymers designed for hot melt adhesives and water dispersions. The distinctiveness of EAA copolymer resin lies in the following areas:

a) Adhesion to aluminium foil;
b) Adhesion to nylon;
c) Hot tack;
d) Heat sealability;
e) Low sealing temperature; and
f) Moisture resistance.

The improved properties offered by EAA copolymer results in flexible packages with improved performance in areas such as seal integrity (few leakers). EAA copolymer through extrusion coating or co-extrusion in blown or cast films may be combined with other polymers to give film structures. Potential film structures include nylon/EAA copolymer, polyester/aluminium foil/EAA copolymer, high density polyethylene (HDPE)/EAA copolymer, biaxially oriented polypropylene/EAA copolymer and low density polyethylene (LDPE)/EAA/ aluminium foil/EAA copolymer.

Plastics are used on a large scale for packaging of foodstuffs and pharmaceuticals. Where direct contact occurs between the packed commodity and the plastics, the high molecular mass polymer itself, being inert and essentially insoluble in food does not pose a toxic hazard. There is, however, a likelihood that some transfer of polymer additives, adventitious impurities such as monomers, catalyst remnants and residual polymerization solvents and low molecular mass polymer fractions may occur from plastics into the packaged material with consequent toxic hazard to the consumers. The occurrence of acute toxicity due to plastic materials in contact with food is most unlikely since only trace quantities of potentially toxic materials are likely to migrate. However, accumulation of these toxic materials with time may lead to hazards, which may be serious.

This standard is intended to be used with the series of standards on plastics for food contact applications given in Annex D. It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as to fabricators of thermoplastic packaging materials to derive maximum benefits. Besides, it may also serve as a basis for official agencies to frame suitable legislation to ensure effective safeguards for the safety and health of consumers where thermoplastics for food contact applications are concerned.

The composition of the Committee responsible for the formulation of this standard is given in Annex E.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

ETHYLENE ACRYLIC ACID (EAA) COPOLYMERS FOR THEIR SAFE USE IN CONTACT WITH FOOD-STUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard specifies the requirements and methods of sampling and test for ethylene/acrylic acid copolymers (EAA) for the manufacture of plastic items used in contact with foodstuffs, pharmaceuticals and drinking water.

1.2 This standard does not purport to establish suitability of the packaging media with particular foodstuffs, pharmaceuticals and drinking water from other than toxicological considerations.

2 REFERENCES

The standards listed in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the edition indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards.

3 TERMINOLOGY

For the purpose of this standard, the definitions given in IS 2828 and IS 11705 shall apply.

4 REQUIREMENTS

4.1 Basic Resins

4.1.1 *Acrylic Acid Content*

In ethylene acrylic acid copolymers, the acrylic acid content shall not exceed 10 percent by mass, when tested as prescribed in Annex B.

4.1.2 *Additive Concentrates*

The total level of slip agent and/or anti-block agent added to the acid copolymer shall not exceed 25 percent by mass prior to let down.

4.2 Material

The material shall also comply with threshold limit of the manufacturing residues polymerization ingredients. Auxiliary items are prescribed in IS 11705.

NOTE — Complete details of test methods shall be provided by the manufacturer, if required by any competent authority.

4.3 Pigments and Colourants

In case, the coloured material is used for food packaging applications, it shall comply with the list and limits of pigments and colourants prescribed in IS 9833.

4.4 Overall Migration

The material shall also comply with overall migration limits of 60 mg/litre, *Max* of the simulant and 10 mg/dm^2, *Max* of the surface of the material or article when tested by the method prescribed in IS 9845.

4.5 Storage and Control

4.5.1 *Storage*

Plastics materials intended for food contact use shall be stored separately from other materials in closed and properly identified containers.

4.5.2 *Control*

An authorized person shall supervise and control the issue of plastic materials to the process or manufacturing area and shall maintain appropriate written records of the issue of such materials.

4.5.3 Adequate standards of hygiene shall be maintained at all time and plant operators and store men shall be trained in proper hygiene practices.

5 PACKING AND MARKING

5.1 Packing

The material shall be suitably packed with a liner in gunny/paper bags or boxes, or cartons, as agreed between the purchaser and the supplier, in a manner so as to ensure that the items do not become contaminated during storage.

5.2 Marking

5.2.1 Each package shall be clearly marked with the following information:

a) Name and type of the material;
b) Month and year of manufacture; and
c) Name of the manufacturer and/or trade-mark, if any.

5.2.2 *BIS Certification Mark*

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

6 SAMPLING

The method of drawing representative sample of the material and the criteria for conformity shall be as prescribed in Annex C.

ANNEX A

(*Clause* 2)

LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 361 : 2009	Normal butyl alcohol, technical — Specification (*third revision*)
IS 2828 : 2019/ ISO 472 : 2013	Plastics — Vocabulary (*second revision*)
IS 4905 : 2015/ ISO 24153 : 2009	Random sampling and randomization procedures (*first revision*)
IS 9833 : 2018	List of colourants for use in plastics in contact with foodstuffs and pharmaceuticals (*second revision*)
IS 9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*)
IS 11705 : 1986	Positive list of constituents of ethylene acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water

ANNEX B

(*Clause* 4.1.1)

DETERMINATION OF ACID CONTENT OF ETHYLENE ACRYLIC ACID COPOLYMERS

B-1 GENERAL

B-1.1 EAA copolymers possess unusual chemical and physical properties because they contain free acid groups. Since polymer performance in end use applications is a function of the amount of copolymerized acrylic acid, it is important that acid content be determined quantitatively by a suitable method, such as that described herein.

B-1.2 Outline of the Method

This method covers the determination of acid content of ethylene acrylic acid (EAA) copolymers containing 2.5 to 25 mass percent of acrylic acid.

In this method, a weighed specimen is dissolved in a suitable hot solvent and titrated while hot with standard base to a visual equivalence point.

B-2 REAGENTS

B-2.1 Xylene — reagent grade

B-2.2 *n*-Butanol — reagent grade (*see* IS 361)

B-2.3 Mixed Solvent — mix 3 volumes of xylene with 1 volume of *n*-butanol

B-2.4 Tetrabutylammonium Hydroxide — TBAH solution in methanol or benzene, in 1 M concentration

B-2.5 Standard Base 0.1 N — mix 1 volume of 1 M TBAH solution with 9 volumes of mixed solvent

B-2.6 Benzoic Acid — primary standard

B-2.7 Thymol Blue (TB) Indicator (Formula Weight of 466.58)

Prepare 0.5 percent solution by weighing 0.125 g of reagent grade thymol blue (TB) (acid form) into a small beaker, adding 25 ml of mixed solvent and adding 0.268 milli equivalence of 0.1 N base to form a clear red-orange solution. Transfer to a glass dropping bottle.

B-3 APPARATUS

B-3.1 Balance — analytical, accurate to 0.000 1 g

B-3.2 Burette — 25 ml capacity, 0.1 ml subdivisions

B-3.3 Flask — Erlenmeyer, 250 ml, female standard-taper joint, with condenser, reflux and matching male standard-taper joint

B-3.4 Stirrer — magnetic

B-3.5 Hot Plate

B-3.6 Stirring Bar — magnetic, 40 mm long, polytetrafluoroethylene encased

B-4 WARNING

In particular, solvents and titrants are malodorous and flammable and may cause burns to skin, eyes and lungs. Wear proper body and eye protection when handling these materials and conduct all operations in a fume hood from which all possible sources of ignition have been removed.

B-5 PROCEDURE

B-5.1 Standardization of Tetrabutylammonium Hydroxide (TBAH)

B-5.1.1 Weigh 0.2 g to 0.3 g benzoic acid and record its weight to 0.001 g. Transfer to a flask containing a stirring bar, add 100 ml of mixed solvent and stir at room temperature until dissolved.

B-5.1.2 Add 6 drops of thymol blue (TB) indicator and titrate with 0.1 N tetrabutylammonium hydroxide (TBAH) solution to the yellow-to-green-to-blue colour change. Record the titrant volume, V_1, to 0.01 ml.

B-5.1.3 Make a second standardization by repeating **A-5.1.1** and **A-5.1.2.**

B-5.1.4 Determine a solvent blank by following **A-5.1.1** and **A-5.1.2** except omitting the benzoic acid. Record the value, V_2, to 0.01 ml.

B-5.1.5 Calculate titrant normality for each replicate determination as follows:

$$\text{Normality } (N)\text{, meq/ml} = \frac{M/E}{V_1 - V_2}$$

where

M = mass, in g, of benzoic acid;

E = benzoic acid factor = 0.122 1 g/meq;
V_1 = volume, in ml, of titrant for benzoic acid; and
V_2 = volume, in ml, of titrant for blank.

B-5.1.6 Average the two values for titrant normality and record to 0.000 1 meq/ml.

B-5.1.7 Re-standardize every week as solvent loss from titrant may occur readily.

B-5.1.8 Whenever new batches of solvent are ready to use, re-determine the solvent blank.

B-5.2 Estimation of Acid Content

B-5.2.1 Weigh a specimen whose mass is within ± 10 percent of the applicable nominal weights given below and record to 0.000 1 g:

Sl No.	*Expected Percent Acid*	*Specimen Mass, g*
(1)	(2)	(3)
i)	Less than 8	2.0
ii)	8 to 25	0.65

NOTES

1 Below 8 percent acid, it may be possible to achieve greater precision and better defined end points by using a specimen weighing more than 2 g, provided the specimen dissolves completely and stays in solution during titration.

2 At 8 percent acid and above increased precision may be achieved by adjusting specimen mass within 0.65 g to 2.0 g, limits, according to expected acid content.

B-5.2.2 Transfer the weighed specimen to a flask containing a stirring bar and add 100 ml of mixed solvent. Connect the flask to a condenser and begin stirring and rapid heating. When boiling begins, reduce the heat to produce a steady moderate stream of reflux until specimen is dissolved (for 30 min or longer, if necessary).

B-5.2.3 Stop stirring and heating. Transfer flask containing dissolved specimen to an unheated stirrer, begin stirring, add 6 drops of thymol blue (TB) indicator and titrate while hot from a yellow colour through an intermediate green to a final blue colour which persists for 30 s. Record the final titrant volume, V_3, to 0.01 ml.

B-5.2.4 Analyze a second specimen by following **A-5.2.1** to **A-5.2.3** above.

B-6 CALCULATIONS

B-6.1 Calculate acid content for each specimen as follows:

$$A = \frac{(V_3 - V_2)\,(N)\,(E)}{M} \times 100$$

where

A = acid content as acrylic acid, mass percent;
V_3 = volume, in ml, base for specimen;
V_2 = volume, in ml, base for solvent blank;
N = titrant normality, meq/ml;
E = factor for acrylic acid = 0.072 06 g/meq; and
M = mass, in g, of specimen.

B-6.2 Average the two values of A for reporting as acrylic acid content of the sample.

ANNEX C

(*Clause* 6)

SAMPLING OF ETHYLENE ACRYLIC ACID (EAA) COPOLYMER RESINS

C-1 GENERAL

C-1.1 In drawing preparing, storing and handling the samples, the following precautions and directions shall be observed.

C-1.2 Samples shall not be taken in an exposed place.

C-1.3 The sampling instrument, wherever applicable, shall be made of stainless steel or any other suitable material on which the material being sampled shall have no action. The instrument shall be clean and dry.

C-1.4 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

C-1.5 The samples shall be placed in a suitable, clean, dry, air-tight metal or glass containers on which the material has no action. The sample containers shall be of such a size that they are almost completely filled by the sample.

C-1.6 Each sample container shall be sealed air-tight with a stopper after filling and marked with full details of sampling, such as, the date of sampling, the month and year of manufacture of the material, etc.

C-1.7 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

C-2 SCALE OF SAMPLING

C-2.1 Lot

In a single consignment, all packages of the same class, type, form and belonging to the same batch of manufacture shall be grouped together to constitute a lot. If a consignment is known to consist of packages belonging to different batches of manufacture or different forms, the packages belonging to the same batch of manufacture and same form shall be grouped together and each such group shall constitute a lot. The packages may consist of container of EAA copolymer rolls, films or vials.

C-2.2 For ascertaining the conformity of the material to the requirements of this specification, samples shall be tested from each lot separately. The number of packages to be sampled shall depend on the size of the lot and shall be in accordance with co1 (2) and (3) of Table 1.

Table 1 Scale of Sampling

(*Clause* C-2.2)

Sl No. (1)	Number of Packages in the Lot (2)	Sample Size (3)
1	Up to 50	3
2	51 to 150	4
3	151 to 300	5
4	301 to 500	7
5	501 and above	10

These packages shall be selected at random from the lot and in order to ensure the randomness of selection, procedures given in IS 4905 may be followed.

C-3 PREPARATION OF TEST SAMPLES

C-3.1 From each of the packages of material selected, small portions of material shall be drawn with the help of a suitable sampling instrument. The total quantity of material collected from each package shall be sufficient to test all the requirements given in **4**.

C-3.2 In case of packages consisting of containers, vials, rolls or films, the number of items to be selected from a package for testing each of the requirements given in **4**, shall be 1.

C-4 NUMBER OF TESTS

Tests for determining all the requirements given in **4** shall be carried out on the individual test samples.

C-5 CRITERIA FOR CONFORMITY

C-5.1 From the individual test results, the average ($\bar{x}$) and the range (R) shall be calculated as given below:

$$\bar{x} = \frac{\text{Sum of test results}}{\text{Number of tests}}$$

where

R = difference between the maximum and the minimum values of the test results.

C-5.2 The lot shall be declared as conforming to the requirements of various characteristics if:

$$\bar{x} + KR \leq \text{maximum value specified; and}$$

K shall be chosen from the table given below for various sample sizes and *AQL*:

Sl No.	*Sample Size*	*Value of K* *AQL*				
		0.65	1.00	1.50	2.50	4.00
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	3	–	–	–	0.587	0.502
ii)	4	–	0.651	0.598	0.525	0.450
iii)	5	0.663	0.614	0.565	0.498	0.431
iv)	7	0.613	0.596	0.525	0.465	0.405
v)	10	0.755	0.703	0.650	0.579	0.507

ANNEX D

(*Foreword*)

INDIAN STANDARDS ON PLASTICS FOR FOOD CONTACT APPLICATIONS

IS No.	*Title*
IS 9833 : 2018	List of colourants for use in plastics in contact with foodstuffs and pharmaceuticals (*second revision*)
IS 9845 : l998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis
IS 10142 : 1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification (*first revision*)
IS 10146 : 1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 10148 : 2023	Positive list of constituents of polyvinyl chloride (PVC) and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
IS 10149 : 1982	Positive list of constituents of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water
IS 10151 : 2019	Polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification (*first revision*)
IS 10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
IS 10910 : 1984	Polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 11434 : 2023	Ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
IS 11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 11705 : 1986	Positive list of constituents of ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 16738 : 2018	Positive list of constituents for polypropylene, polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals

ANNEX E

(*Foreword*)

COMMITTEE COMPOSITION

Plastics Sectional Committee, PCD 12

Organization	*Representative(s)*
Central Institute of Petrochemicals Engineering & Technology (CIPET), Chennai	PROF (DR) SHISHIR SINHA **(*Chairperson*)**
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Review of Indian Standards

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Amendments Issued Since Publication

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